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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,879	02/08/2002	C. Alexander Turner JR.	LEX-0299-USA	8753

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,879

Applicant(s)

TURNER ET AL.

Examiner

Michael Szperka.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date May 7, 2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group IV, claim 6, in the reply filed on November 1, 2004 is acknowledged.
2. In view of the papers filed November 1, 2004, the inventorship in this nonprovisional application has been changed by the deletion of Xuanchuan (Sean) Yu, Maricar Miranda, and Brian Mathur.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claims 1-5 have been canceled.

Claims 7-11 have been added.

Claims 6-11 are pending in the current application

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. Specifically claim 11 reads on Group I of the restriction requirement dated August 16, 2004.

Claims 6-10 are currently under examination.

It is suggested that the specification be amended to indicate that the benefit of U.S. provisional application 60/267,583 is claimed under 35 USC 119(e).

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

The oath has not been signed.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 6-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant has claimed an isolated polynucleotide that encodes the polypeptide of SEQ ID NO:10, of which SEQ ID NO:9 is a species of such polynucleotide sequences, as well as a vector and a host cell that comprise said sequences. Applicant has asserted that the polypeptide of SEQ ID NO:10, and therefore polynucleotides encoding said sequence, have utility because they share structural similarity with mammalian proteins having structural domains in common with proteins of the immunoglobulin superfamily (see page 2, lines 1-6). The identification of a protein as a member of the

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immunoglobulin superfamily does not provide a specific and substantial utility for the polypeptide of SEQ ID NO: 10.

It is known in the art that the immunoglobulin (Ig) superfamily is the most abundant family of cell surface molecules, accounting for 50% of leukocyte surface glycoproteins (Holness et al., J. Cell Sci. 1994, 107:2065-2070, see entire document, particularly the first paragraph of the left column of page 2065). Ig superfamily members often have different functions, including serving as receptors for growth factors, serving as receptors for the Fc region of antibodies, and serving as adhesion molecules. These are broad categories that encompass further functional divisions. For example, the molecular interactions between family members considered to be adhesion molecules consists of molecules involved in antigen presentation (CD4 with MHC class II and CD8 with MHC class I), T cell costimulation (CD28/CTLA4 with B7.1 and B7.2) integrin-mediated cell-cell interactions, and other biological functions (Holness et al., see particularly the first and last paragraphs of page 2065). All members of the Ig superfamily share a common shape or protein fold, yet the surface that is used by Ig superfamily members to interact with other proteins is considerably variable. As such, identification of a molecule as a member of the Ig superfamily does not indicate a specific utility for the protein since such an identification does not indicate how the protein functions or what surface or surfaces are critical for maintenance of that function (Holness et al., particularly the last paragraph of page 2068). Therefore, one cannot know the function of the polypeptide of SEQ ID NO:10 without conducting additional research.

The specification also indicates that the polypeptide of SEQ ID NO:10 is useful for the production of agonists and antagonists specific for SEQ ID NO:10. Such a utility is also not specific or credible since as was indicated above, knowing that a molecule is a member of the Ig superfamily does not correlate with a specific biological function. Identification of a molecule as an agonist or antagonist of SEQ ID NO:10 requires the ability to measure the activity of SEQ ID NO:10 in the presence of potential agonists or antagonists. Since the activity of SEQ ID NO:10 is not disclosed, it is impossible to identify agonists or antagonists of SEQ ID NO:10 that modify its activity. It is possible to identify compounds that modulate the expression of SEQ ID NO:10 as compared to basal expression levels, but without knowledge of the function of SEQ ID NO:10 a person of skill in the art would have no reason to modulate the expression of SEQ ID NO:10 except for the purpose of further experimentation. Similarly, Applicant has not provided a reason why a skilled artisan would want to make a transgenic mouse that either overexpresses the polypeptide of SEQ ID NO:10 or lacks expression of SEQ ID NO:10, be it through antisense or "knock-out" technologies, other than to further study and characterize the polypeptide of SEQ ID NO:10.

The final disclosed utilities relate to the use of a polynucleotide sequence that encodes SEQ ID NO:10 to be used as chromosomal marker. Applicant indicates on page 18, lines 7-9 that the gene that encodes SEQ ID NO:10 is located somewhere on human chromosome 11. Applicant also discloses many nucleotide polymorphisms for this gene between page 18, line 17 and page 19, line 11, and indicates that these sequences may be useful in restriction length polymorphism analysis (RLFP) and

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forensic biology. Such utilities based on the polynucleotide sequences that encode SEQ ID NO:10 are not specific or credible. This is because while the gene encoding SEQ ID NO:10 may reside on chromosome 11, its precise location is not known. More importantly, no information is provided to indicate that the gene that encodes SEQ ID NO:10 is in any way associated with an identifiable human disease or condition that might be identified by assays that utilize polynucleotides corresponding to SEQ ID NO:10. Further, all of the identified polymorphisms for this gene lack utility because a person of skill in the art would not be able identify the significance of an RLFP analysis that utilized these polymorphisms without first conducting additional research to identify a specific human disease or condition that correlates with one or more of these polymorphic markers.

Since the specification does not appear to indicate a specific and substantial utility for the polypeptide of SEQ ID NO:10 or for polynucleotides that encode said polypeptide, a person of skill in the art would not know what to do with the polypeptide of SEQ ID NO:10 or a polynucleotide that encodes said polypeptide without conducting additional research. Therefore, the claimed invention lacks a specific and substantial utility.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 6-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, if Applicant intends the phrase "wherein said nucleic acid molecule has the sequence of SEQ ID NO:9" to be open, the word 'comprising' should be used in place of 'has', while if Applicant intends the claim to be closed, the phrase 'consisting of' should replace 'has' in the claim. Appropriate correction is required.

10. Claim 9 recites the limitation "said nucleic acid sequence". There is insufficient antecedent basis for this limitation in the claim because claim 8 contains the limitation of a nucleotide sequence, not a nucleic acid sequence. Appropriate correction is required.

11. No claims are allowed.


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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 1, 2004


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